

04-04-05

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PATENT
Customer No. 22,852
Attorney Docket No. 08981.0003-00000

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Signed: _____

Stephanie Liva

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: _____)

Jia-Ning XIANG et al.)

Group Art Unit: 1625

Application No.: 10/728,942)

Examiner: Bernard I. DENTZ

Filed: December 8, 2003)

For: CARBIDOPA PRODRUGS AND)
DERIVATIVES, AND)
COMPOSITIONS AND USES)
THEREOF)

Confirmation No.: 9013

Mail Stop Amendment
Commissioner for Patents
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Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R.
§ 1.97(b)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants bring to the attention of the Examiner the documents on the attached listing. This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits for the above-referenced application.

Copies of the documents are attached.

On May 5, 2004, Applicants submitted a Supplemental Information Disclosure Statement to bring to the Examiner's attention the documents that had been cited in a counterpart Patent Cooperation Treaty application. Two of the documents were not in the English language, and, although the IDS indicated that the PCT search report was being submitted, that search report was not listed on the 1449 form. Accordingly, Applicants provide in this submission:

1. For German patent DD 240 818, we provide certified translations of both the abstract and the example noted in the search report.

2. For German patent DE 2 062 285, we provide the priority documents we were able to obtain. These documents are in the English language. They are as follows:

Patent number	Application number	Filing date
US 3,676,480	13,770	February 24, 1970
US 3,715,382	9,052	February 5, 1970
CA 919691	78,424	March 25, 1970
CA 929483	78,420	March 25, 1970
CA 951661	78,419	March 25, 1970
CA 951662	78,421	March 25, 1970
CA 956969	78,417	March 25, 1970
CA 971974	78,423	March 25, 1970

The PTO/SB/08 lists these documents and the search report. In addition, the PTO/SB/08 lists references cited in the specification of the present application and not yet submitted in an Information Disclosure Statement.

Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

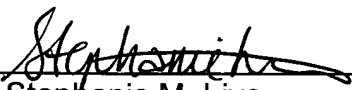
Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

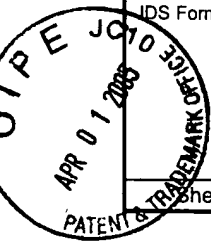
If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: April 1, 2005

By: 
Stephanie M. Liva
Reg. No. 54,278
Customer No. 22,852



IDS Form PTO/SB/08: Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 4

Complete if Known

Application Number	10/728,942
Filing Date	December 8, 2003
First Named Inventor	Jia-Ning XIANG et al.
Art Unit	1625
Examiner Name	Bernard I. Dentz
Attorney Docket Number	08981.0003-00000

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS

Examiner Initials	Cite No. ¹	Document Number	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
		2,996,431	08-15-1961	Barry	
		3,139,383	06-30-1964	Neville	
		3,402,240	09-17-1968	Cain et al.	
		3,676,480	07-11-1972	Sletzinger et al.	
		3,715,382	02-06-1973	Karady et al.	
		3,811,444	05-21-1974	Heller et al.	
		3,845,770	11-05-1974	Theeuwes et al.	
		3,916,899	11-04-1975	Theeuwes et al.	
		3,962,414	06-08-1976	Michaels	
		3,992,518	11-16-1976	Chien et al.	
		4,063,064	12-13-1977	Saunders et al.	
		4,066,747	01-03-1978	Capozza	
		4,070,347	01-24-1978	Schmitt	
		4,079,038	03-14-1978	Choi et al.	
		4,083,949	04-11-1978	Benedikt	
		4,088,864	05-09-1978	Theeuwes et al.	
		4,093,709	06-06-1978	Choi et al.	
		4,200,098	04-29-1980	Ayer et al.	
		4,285,987	08-25-1981	Ayer et al.	
		4,311,706	01-19-1982	Bodor et al.	
		4,421,736	12-20-1983	Walters	
		4,434,153	02-28-1984	Urquhart et al.	
		4,721,613	01-26-1988	Urquhart et al.	
		4,752,470	06-21-1988	Mehta	
		4,816,263	03-28-1989	Ayer et al.	
		4,820,523	04-11-1989	Shtohryn et al.	
		4,826,875	05-02-1989	Chiesi	
		4,853,229	08-01-1989	Theeuwes	
		4,966,915	10-30-1990	Tsuchiya et al.	
		5,017,607	05-21-1991	Chiesi	
		5,462,933	10-31-1995	Kramer et al.	
		5,607,969	03-04-1997	Milman et al.	
		5,840,756	11-24-1998	Cohen et al.	

IDS Form PTO/SB/08: Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/728,942
				Filing Date	December 8, 2003
				First Named Inventor	Jia-Ning XIANG et al.
				Art Unit	1625
				Examiner Name	Bernard I. Dentz
Sheet	2	of	4	Attorney Docket Number	08981.0003-00000

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS					
		6,051,576	04-18-2000	Ashton et al.	
		6,171,615	01-09-2001	Roussin et al.	
		6,375,987	04-23-2002	Farah et al.	
		6,379,700	06-14-2001	Joachim et al.	
		2002/0099041 (publication of application 09/972,411, a non-provisional application of 60/238,758)	07-25-2002	Gallop et al.	

Note: Copies of the U.S. Patent Documents are not Required in IDS filed after October 21, 2004

FOREIGN PATENT DOCUMENTS						
Examiner Initials ⁶	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
		CA 919691	01-23-1973	Merck & Co., Inc.		
		CA 929483	07-03-1973	Merck & Co., Inc.		
		CA 951661	07-23-1974	Merck & Co., Inc.		
		CA 951662	07-23-1974	Merck & Co., Inc.		
		CA 956969	10-29-1974	Merck & Co., Inc.		
		CA 971974	07-29-1975	Merck & Co., Inc.		
		DE 2 062 285	07-01-1971	Merck & Co., Inc.		Yes- certain priority documents are listed/provided
		DD 240 818	11-19-1986	Schmitz et al.		Yes-Abstract and Example 14 only
		WO 95/20567 A1	08-03-1995	University of Kentucky Research Foundation		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation ⁶
	1.	International Search Report for PCT/US03/38742, dated March 30, 2004 (5 pages).	
	2.	CHENG and FUNG, "Dose-Dependent Pharmacokinetics of Laevodopa and its Metabolites in the Rat," <i>Xenobiotica</i> , 6(4):237-248 (1976).	
	3.	KURLAN et al., "Duodenal and Gastric Delivery of Levodopa in Parkinsonism," <i>Ann. Neurol.</i> , 23(6):589-595 (1988).	
	4.	IWAMOTO et al., "Effect of Age on Gastrointestinal and Hepatic First-Pass Effects of Levodopa in Rats," <i>J. Pharm. Pharmacol.</i> , 39:421-425 (1987).	
	5.	Entry on Sinemet® in <i>Physicians' Desk Reference</i> , 56th Edition (2002).	
	6.	YEH et al., "Pharmacokinetics and Bioavailability of Sinemet CR: A Summary of Human Studies," <i>Neurology</i> , 39(Suppl. 2):25-38 (1989).	
	7.	SANDLER et al., "Variation of Levodopa Metabolism with Gastrointestinal-Absorption Site," <i>The Lancet</i> , 1(7851):238-240 (1974).	

IDS Form PTO/SB/08: Substitute for form 1449A/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application Number	10/728,942
				Filing Date	December 8, 2003
				First Named Inventor	Jia-Ning XIANG et al.
				Art Unit	1625
				Examiner Name	Bernard I. Dentz
Sheet	3	of	4	Attorney Docket Number	08981.0003-00000

NON PATENT LITERATURE DOCUMENTS		
8.	"SkyePharma's Medopar-DR approved," <i>Scrip</i> , 2233:21 (1997).	
9.	JUNCOS et al., "Levodopa Methyl Ester Treatment of Parkinson's Disease," <i>Neurology</i> , 37:1242-1245 (1987).	
10.	COOPER et al., "L-Dopa Esters as Potential Prodrugs: Effect on Brain Concentration of Dopamine Metabolites in Reserpinized Mice," <i>J. Pharm. Pharmacol.</i> , 39:809-818 (1987).	
11.	GRAUL, "The Year's New Drugs," <i>Drug News Perspect.</i> , 14(1):12-31 (2001).	
12.	FIX et al., "Short-Chain Alkyl Esters of L-Dopa as Prodrugs for Rectal Absorption," <i>Pharm. Res.</i> , 6(6):501-505 (1989).	
13.	FIX et al., "A Comparison of Oral and Rectal Absorption of L-Dopa Esters in Rats and Mice," <i>Pharm. Res.</i> , 7(4):384-387 (1990).	
14.	LEPPERT et al., "The Effects of Carbidopa Dose and Time and Route of Administration on Systemic L-Dopa Levels in Rats," <i>Pharm. Res.</i> , 5(9):587-591 (1988).	
15.	CONTIN et al., "Pharmacokinetic Optimisation in the Treatment of Parkinson's Disease," <i>Clin. Pharmacokinet.</i> , 30(6):463-481 (1996).	
16.	LU and YU, "Dimensionless Presentation for Drug Release from a Coated Pure Drug Bead: 2. Experiment," <i>Int. J. Pharm.</i> , 112:117-124 (1994).	
17.	FELMEISTER, "Powders," in <i>Remington's Pharmaceutical Sciences</i> , Mack Publishing Company, Fourteenth Edition, Chapter 86, pp. 1626-1628 (1970).	
18.	FINCHER, "Particle Size of Drugs and Its Relationship to Absorption and Activity," <i>J. Pharm. Sci.</i> , 57(11):1825-1835 (1968).	
19.	KING and SCHWARTZ, "Oral Solid Dosage Forms," in <i>Remington's Pharmaceutical Sciences</i> , Mack Publishing Company, Chapter 90, pp. 1603-1625 (1985).	
20.	SEFTON, "Implantable Pumps," <i>CRC Crit. Rev. Biomed. Eng.</i> , 14(3):201-240 (1987).	
21.	SAUDEK et al., "A Preliminary Trial of the Programmable Implantable Medication System for Insulin Delivery," <i>N. Engl. J. Med.</i> , 321(9):574-579 (1989).	
22.	LANGER and PEPPAS, "Chemical and Physical Structure of Polymers as Carriers for Controlled Release of Bioactive Agents: A Review," <i>J. Macromol. Sci. Rev. Macromol. Chem. Phys.</i> , C23(1):61-126 (1983).	
23.	LEVY et al., "Inhibition of Calcification of Bioprosthetic Heart Valves by Local Controlled-Release Diphosphonate," <i>Science</i> , 228:190-192 (1985).	
24.	DURING et al., "Controlled Release of Dopamine from a Polymeric Brain Implant: In Vivo Characterization," <i>Ann. Neurol.</i> , 25:351-356 (1989).	
25.	HOWARD et al., "Intracerebral Drug Delivery in Rats with Lesion-Induced Memory Deficits," <i>J. Neurosurg.</i> , 71:105-112 (1989).	
26.	ALDERMAN, "A Review of Cellulose Ethers in Hydrophilic Matrices for Oral Controlled-Release Dosage Forms," <i>Int. J. Pharm. Tech. & Prod. Mfr.</i> , 5(3):1-9 (1984).	
27.	BAMBA et al., "Release Mechanisms in Gelforming Sustained Release Preparations," <i>Int. J. Pharm.</i> , 2:307-315 (1979).	
28.	GOODSON, "Dental Applications" in <i>Medical Applications of Controlled Release, Volume II: Applications and Evaluation</i> , Langer and Wise (Eds.), CRC Press, Inc., Chapter 6, pp. 115-138 (1984).	
29.	LANGER, "New Methods of Drug Delivery," <i>Science</i> , 249:1527-1533 (1990).	
30.	LINHARDT, "Biodegradable Polymers for Controlled Release of Drugs," in <i>Controlled Release of Drugs: Polymers and Aggregate Systems</i> , Rosoff (Ed.), VCH Publishers, Chapter 2, pp. 53-95 (1989).	
31.	COLEMAN et al., "Polymer Reviews: A Practical Guide to Polymer Miscibility," <i>Polymer</i> , 31:1187-1203 (1990).	
32.	HOES and FEIJEN, "The Application of Drug-Polymer Conjugates in Chemotherapy," in <i>Horizons in Biochemistry and Biophysics, Volume 9: Drug Carrier Systems</i> , Roerdink and Kroon (Eds.), John Wiley & Sons, Chapter 3, pp. 57-109 (1989).	
33.	LEONG and LANGER, "Polymeric Controlled Drug Delivery," <i>Adv. Drug Delivery Rev.</i> , 1:199-233 (1987).	
34.	VERMA et al., "Osmotically Controlled Oral Drug Delivery," <i>Drug Dev. Ind. Pharm.</i> , 26(7):695-708 (2000).	

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				<i>Examiner Name</i>	Bernard I. Dentz
Sheet	4	of	4	<i>Attorney Docket Number</i>	08981.0003-00000

Examiner Signature		Date Considered	
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.